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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/913,430	12/09/97	WALKER J	U011415-0

HM12/1124

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EXAMINER	
SWARTZ,R	
ART UNIT	**PAPER NUMBER**
1641	17

DATE MAILED: 11/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/913,430	Walker et al
Examiner	**Group Art Unit**
Rodney P. Swartz, Ph.D.	1641

☒ Responsive to communication(s) filed on *9September1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *44-74* is/are pending in the application.

Of the above, claim(s) *53-59, 67, and 70-72* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *44-52, 60-66, 68, 69, 73, and 74* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, paper#9, received 17September1998, is acknowledged. Applicants elect, with traverse, Group I, claims 44-52, 60-66, 68, 69, 73 and 74, drawn to mycoplasma antigen.

The traversal is on the grounds that the inventions of Groups II and III can be easily derived once the antigen of Group I is identified. This is not found persuasive because of reasons of record (Office Action, 13July1998, paper#7).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 44-74 are pending. Claims 53-59, 67, and 70-72 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

3. Claims 44-52, 60-66, 68, 69, 73 and 74 are under consideration.

Specification

4. The disclosure is objected to because of the following informalities:

a) the quality of print throughout the entire specification and claims is poor to the point that it is uncertain what words are actually printed. For examination purposes, the examiner has interpreted the poor print, but, **a substitute specification, in good print quality, is required,**

b) page 1, line 26, "colonisation" should be "colonization",

c) page 6, line 20, "titres" should be "titers"; line 28, "hypneumoniae" should be hyopneumoniae",

d) page 11, line 13, "hypneumoniae" should be hyopneumoniae",

e) page 18, line 4, "summarised" should be "summarized",

f) page 20, line 23, "immunised" should be "immunized"; line 26, "immunising" should be "immunizing",

g) page 21, line 2, "aluminium" should be "aluminum"; line 5,"immunising" should be "immunizing",

h) page 23, line 2, "immunised" should be "immunized"; line 6, "resolubilised" should be "resolubilized"; line 8, "immunisation" should be "immunization",

I) page 24, line 14, "immunisation" should be "immunization",

Appropriate correction is required.

Drawings

5. This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth on the attached form PTO-948.

Claims

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 45-52 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 45-52 do not recite phrases which distinguish the claimed antigen from a product of nature, e.g., "isolated" or "purified".

8. Claims 44-52, 60. 61, 64, 65, 66, 68, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps of indication protection. The claims are directed to methods of preparation of "putative protective" antigens from *Mycoplasma* by utilizing antibodies which bind to any antigen of *Mycoplasma*. The antibodies are produced by cells extracted from lesion sites, infection sites, or areas close to the infection or lesion sites. However, there is no methods steps to distinguish between antibodies which bind to "protective" antigens from antibodies which bind to other *Mycoplasma* antigens. Therefore, the claims do not contain any method steps to distinguish between "any" antigen and "protective" antigens.

9. Claims 44-52, 60-61, 64-66, 68-69 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is meant by a "putative" protective antigen. Either the antigen is protective, or it is not protective.

10. Claims 62 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62 and 73 are dependent upon nonelected claims and refer for descriptive criticalities to the nonelected claims. Therefore, it is clear what is meant in claim 62 by "antibody according to claim 54", and in claim 73, "DNA fragment according to claim 70". It is recommended that those criticalities to which claims 62 and 73 refer in the nonelected claims be incorporated into claims 62 and 73.

11. Claims 44, 62, 63, and 64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies produced from antibody producing cells, does not reasonably provide enablement for antibodies produced from non-antibody producing cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant claims are directed to antibody production by isolating "cells" from a biological sample, culturing said cells *in vitro* and harvesting antibodies produced from said cells. However, there is no restriction that the cells be actually antibody producing cells. The specification is silent concerning producing antibodies from cells so isolated which are not normally known to produce antibodies, e.g., macrophages, T-lymphocytes, granulocytes, epithelial cells, etc.

12. Claims 45, 52, 63, 65, 66, 68, and 69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically delineated antigens, does not reasonably provide enablement for mutants, derivatives, and fragments thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches specific antigens isolated from *Mycoplasma hyopneumoniae* which are reduce lung lesions in infected pigs. However, the specification does not teach the criticalities of the antigens which are necessary for the protection, and therefore the specification does not provide guidance in producing mutants, derivatives and fragments thereof which would maintain the functionality of protectiveness.

13. Claims 44-52, 60-66, 68, 69, 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protection of pigs against *Mycoplasma hyopneumoniae*, does not reasonably provide enablement for protection of *all* subjects. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches reduction of lung lesions only in pigs. The specification is silent concerning methodologies, doses, regimens, or results in any other subject.

14. Claims 44 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44 and 60 recite "probing the *Mycoplasma* sample with the antibody probe to detect **at least one** antigen; and isolating the antigen detected. It is unclear how such isolation occurs if the antibody probe detects more than one antigen, commensurate with the descriptive language of "at least" one.

15. Claims 45 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims 45 and 63 appear to have spaces following "(kd)," but preceding "mutants". It is unclear if the is purposeful or if something has been omitted.

16. Claims 46, 47, 48, 49, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what amino acids are designated by "X" in the sequences and what is meant by "(F/I)(R/E), (V/A)" "(Q/A)" and "(M/N)".

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 45, 46, 47, 65, 66 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Faulds et al (U.S. Pat. No. 5,252,328).

Faulds et al teach a protective antigen against *Mycoplasma hyopneumoniae* having an approximate molecular weight of 72-75 kilodaltons (74.5 kda)(Abstract; Example 4), which, in the absence of evidence to the contrary, would comprise the sequences listed.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703)308-4027. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

RODNEY P. SWARTZ, PH.D
PATENT EXAMINER

Art Unit 1641

November 22, 1999